(54) Title: A CLINICAL INFORMATION REPORTING SYSTEM
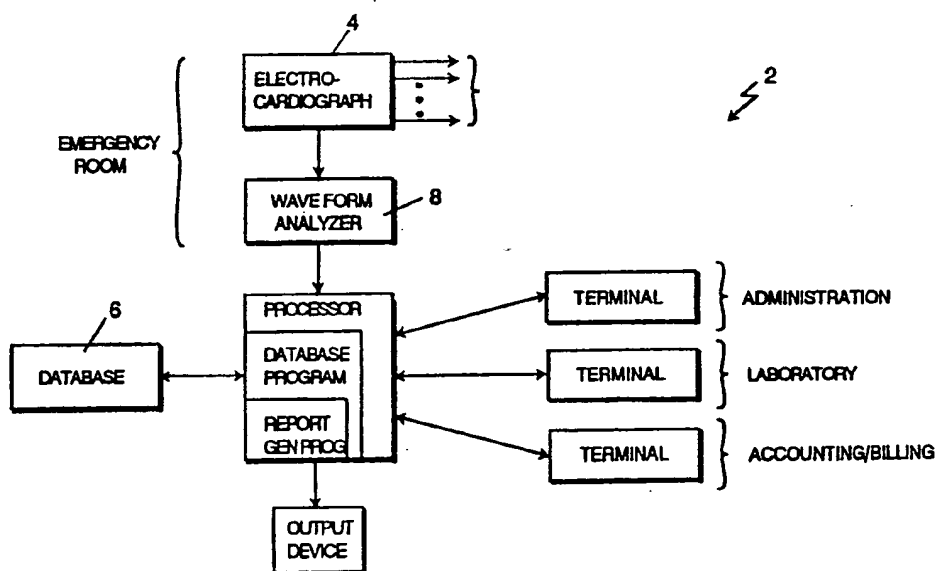
(57) Abstract

A clinical information reporting system (2) for use with an electronic database (6) for a health care facility, the electronic database containing records for a group of patients and operational information which is accessed and used during the course of operation of the facility, the records containing clinical information for said group of patients, the reporting system (2) including an electrocardiograph (4) which generates ECG-related data for the group of patients; database application logic for incorporating the ECG-related data for the group of patients into the database (6); and report generating logic for generating a process of care report from the information stored in the database (6), the process of care report presenting selected process of care information derived from the database as a function of a clinically meaningful class of the group of patients, wherein the clinically meaningful class is defined at least in part in terms of the ECG-related data supplied by the electrocardiograph (4) and stored within the database (6).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	ML	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic	SE	Sweden
CH	Switzerland		of Korea	SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad.
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		
ES	Spain	MG	Madagascar		

- 1 -

A CLINICAL INFORMATION REPORTING SYSTEM
Background of the Invention

The invention relates to clinical information reporting systems.

5   Each year, over 500,000 Americans die of acute myocardial infarction (AMI, known as "heart attack"), including over 200,000 in hospitals. Were the medical advances of the last two decades consistently used, the mortality rate for hospitalized AMI patients would be

10 much less. Medical care in this country's 6,000 hospitals varies, and current national AMI mortality rates are about twice those reported from major research centers. The problem is that physicians and hospitals do not consistently deliver optimal cardiac care.

15   Two fundamental problems underlie the failure to translate medical advances into results in this country's hospitals: 1) delays and errors in emergency room (ER) physician decision-making about the immediate care of the AMI patient, and 2) the lack of any credible and

20 practical way to monitor and evaluate hospital AMI care results.

     The key advances in AMI care relate to the very first hours of care: new medications and procedures for immediate use, and admission to the coronary care unit

25 (CCU). Even short delays in treatment can cost lives in the first few hours, as can mistakes in CCU admission, but both are currently common. Delays occur as ER physicians try to sort out and treat AMI patients from among the many others they must evaluate. For example,

30 the typical ER delay in giving thrombolytic therapy is about two hours, despite its well-known loss of its life-saving effect if not given promptly. Admission decisions to the CCU are also often suboptimal. Of the early 1.5 million patients admitted to CCUs in this country each

- 2 -

year, fewer than half have true acute cardiac ischemia
(the diagnosis including AMI as well as "unstable angina
pectoris", which can quickly progress to an AMI), thus
filling CCUs with unnecessary admissions. More costly in

5   lives, each year approximately 20,000 AMI patients are
inadvertently sent home from the ER without any care.
        Once primarily the concern of physicians and
researchers, because of the scale of the problem, the
Federal government is now looking for ways to monitor,

10   evaluate and improve the delivery of AMI care. Over the
past two years, separate expert panels have been convened
by the Health Care Financing Administration (HCFA), the
Agency for Health Care Policy and Research (AHCPR), the
National Institutes of Health (NIH), and the Institute of

15   Medicine of the National Academy of Science, to find ways
to improve the delivery of cardiac services. In each
case, these panels and agencies have concluded that two
major approaches are needed: 1) in order to improve the
quality and speed of physicians' emergency care of AMI

20   patients, methods are needed to assist physicians'
emergency decision-making; and 2) in order to detect
suboptimal care and to encourage continuous improvement,
methods are needed to objectively assess the quality of
physicians' and hospitals' AMI care.

25   Summary of the Invention
        In general, in one aspect, the invention features
a clinical information reporting system for use with an
electronic database in a health care facility. The
electronic database contains records for a group of

30   patients and it contains operational information which is
accessed and used during the course of operation of the
facility. The patient records include clinical
information for the group of patients. The reporting
system includes an electrocardiograph which generates

- 3 -

ECG-related data for the group of patients; database
application logic for incorporating the ECG-related data
for the group of patients into the database; and report
generating logic for generating a process of care report

5 from the information stored in the database. The process
of care report presents selected process of care
information derived from the database as a function of a
clinically meaningful class of patients, wherein
clinically meaningful class is defined at least in part

10 in terms of the ECG-related data supplied by the
electrocardiograph and stored within the database.

Preferred embodiments include the following
features. Each of the patient records for a group of
patients contains non-ECG related clinical information

15 and the clinically meaningful class is defined in terms
of the ECG-related data and non-ECG related clinical
information stored within the database. The non-ECG
related clinical information includes laboratory test
results of blood enzyme analyses and the clinically

20 meaningful class is defined in terms of the ECG-related
data and the presence of an abnormal blood enzyme as
indicated by the laboratory test results stored in the
database. The abnormal blood enzyme is CPK. The
database includes administrative information which is

25 accessed and updated during the course of operation of
the health care facility and the process of care
information is derived at least in part from that
administrative information. The database also includes
patient billing information which is accessed and updated

30 during the course of operation of the health care
facility and the process of care information is derived
at least in part from that patient billing information.
The database contains triage decisions for the group of
patients and the process of care report reports triage

- 4 -

decisions for the clinically meaningful class of the group of patients.

In general, in another aspect, the invention features a clinical information reporting system including an electrocardiograph which generates ECG-related data for the group of patients; a predictive instrument which receives from the electrocardiograph ECG data for each patient of the group of patients and which computes a probability for each patient therefrom, the computed probability being a probability that patient is experiencing a cardiac problem; database application logic for incorporating the ECG-related data for the group of patients and the computed probability for each patient into the database; and report generating logic for generating a process of care report from the information stored in the database, the process of care report presenting selected process of care information derived from the database as a function of the computed probabilities supplied by the predictive instrument.

The invention gives the health care facility the ability to access and view operational, clinical and process of care information within its electronic databases in terms of meaningful clinical classes for cardiac patients. The availability of both patient ECG data and other clinical information (e.g., laboratory enzyme analysis for patients) within the same database enables the user of the database to sort and present information in terms of clinical classes that are defined on the basis of both ECG data and non-ECG data. Since the patient information can now be accessed in terms of meaningful clinical classes defined at least in part by the ECG data, the user can generate process of care reports that would be very useful for risk management, quality assurance, utilization review and physician feedback purposes. Thus, the invention enables the

- 5 -

health care facility to much more effectively monitor and
evaluate clinical care that is provided to cardiac
patients.

    Furthermore, such reports can be generated within
5   the clinical setting and during the time frame in which
they are needed (i.e., in real-time). The generation of
such reports does not require the intervention of medical
records clerks who must generate diagnostic codes for
each patient based upon sometimes subjective and
10 incomplete information supplied by the treating
physician. Previously, if such reports had been desired,
they could not be obtained in a timely manner but only
through long, expensive research studies that required
considerable manual effort and subjective or imprecise
15 determinations of the diagnostic codes for the patients
(i.e., the clinical class to which the patient belongs).

    Also, in embodiments of the invention which
incorporate a predictive instrument, the inclusion in the
general database of the probability generated by the
20 predictive instrument (e.g. the probability that acute
ischemic heart disease is present) provides another
useful and valuable variable for reporting and evaluating
process of care information that can also be extracted
from that database.

25   Other advantages and features will become apparent
from the following description of the preferred
embodiment and from the claims.

              Description of the Preferred Embodiment

    Fig. 1 is a block diagram of a clinical reporting
30 system;

    Fig. 2 presents the coefficients and variables of
the logistic regression model used to compute the
probability of acute cardiac ischemia;

- 6 -

Fig. 3 is an example of a process of care report which may be generated from the database using ECG data to identify the relevant patient population (i.e., AMI patients);

5   Fig. 4 is an example of another process of care report which may be generated from the database based upon predictive instrument generated ACI probabilities for the cardiac patients;

Fig. 5 is an example of a report of mean ACI

10   probability by triage decision and by physician; and

Fig. 6 is an example of a report of mean ACI probability by triage decision and by resident training year.

Structure and Operation

15   Referring to Fig. 1, in a clinical information reporting system 2, ECG-related data generated by an electrocardiograph 4 is incorporated into a database 6 which also contains other clinical information about patients seen at a health care facility, as well as

20   operational information for the facility. Electrocardiograph 4 produces a digitized ECG waveform for the patient being monitored. The ECG waveform is processed by a waveform analyzer 8 which identifies and quantifies its important characteristics and features.

25   Electrocardiograph 4 and waveform analyzer 8 may be part of a single instrument, for example, a Hewlett Packard Pagewriter XLi®, which is a 80386-based self-interpreting electrocardiograph. The Pagewriter generates an output referred to as a "BLOB" (Binary Large OBject), which

30   contains the digitized waveform as well as a measurement matrix containing the results of the waveform analysis.

The output of waveform analyzer 8 passes to a predictive instrument 10 which evaluates the condition of the patient and generates a probability that the patient

- 7 -

is, for example, experiencing a particular type of
cardiac condition. Predictive instrument 10 is designed
in accordance with the design principles used for
building other predictive devices such as the device for
5   determining the probability of imminent death of the
patient from cardiovascular disease such as is described
in U.S. 4,957,115 to Dr. Harry P. Selker and the hand-
held predictive instrument described by Michael W. Pozen
et al. in "A Predictive Instrument to Improve Coronary-
10   Care-Unit Admission Practices in Acute Ischemic Heart
Disease" The New England Journal of Medicine, Vol 310 pp.
1273-1278, May 17, 1984, both of which are incorporated
herein by reference.

        In the described embodiment, predictive instrument
15   10 is a TIPI (time-insensitive predictive instrument)
which uses a logistic regression-based equation for
computing the probability that the patient is
experiencing acute cardiac ischemia. The logistic
regression equation is of the form:

20       $P = 100 \times [1-1/(1+\exp(b_0 + \Sigma\ b_i x_i))]$,

where P is the probability of acute cardiac ischemia, b_0
is a constant, and the b_i's are coefficients of the
variables x_i which are included in the model.

        The variables which are used in this equation are
25   shown in Fig. 2 along with the values of the coefficients
and the values which the x_i's can take for the different
variables. Note that only the largest x is used per
variable. Also ECG findings must be present in at least
two leads, and S-T segment and T wave changes are
30   "normal" if secondary to right or left complete bundle
branch blocks, left ventricular hypertrophy, or a paced
QRS. Only one type of abnormality is coded each for S-T
segment and for T wave per patient (exclusive of
TWISTDEP), use with elevation taking priority.

- 8 -

Deviations are expressed in mm using the standard ECG
scale of 1mm = 0.1 mV.

The computer uses the inputs from
electrocardiograph 4, waveform analyzer 8 to

5   automatically compute the relevant probability using the
above equation. The probability can be computed either
in real time, while the patient is being evaluated, or it
may be computed retrospectively.

The user performs the ECG in the usual way. At

10   the time the ECG is being obtained, the user also enters
patient identifying information and simple clinical data
into the electrocardiograph. This includes, for example,
patient date of birth, hospital ID #, age, sex, often a
single diagnostic or symptomatic label (e.g. "chest

15   pain", or "history of heart attack", etc.) medications,
blood pressure, weight and perhaps other items which may
be required by the computation that is to be performed by
the predictive instrument.

The digitized ECG waveform, along with output from

20   waveform analyzer 8, the computed probability from
predictive instrument 10 and patient identifiers and
other data which have been entered through
electrocardiograph 4 by the physician are processed by a
digital processor 12 which is running a database software

25   program 14 such as, for example, the relational database
program available from Sybase, Inc. and present in the
Hewlett Packard ECG management system known as
Tracemaster®. Database software program 14 opens the
appropriate file and adds the information to patient

30   records stored to database 6. If database 6 contains a
record for the relevant patient, database program 14 adds
the ECG-derived information to the existing record for
that patient. If database 6 does not yet include a
record for the patient, database program 14 creates a new

record for the patient, and stores the ECG-derived
information in that new record.

Database 6 also contains non-ECG clinical
information for patients including, for example, enzyme
5   analysis, blood test results, urinalysis results, blood
pressure readings, etc. which have been gathered during
the evaluation and testing of the patients by the medical
staff at the facility. Such non-ECG clinical information
may be entered into database 6 in any of a number of
10   different ways. For example, it may be automatically
entered via a direct hook up with the laboratory assay
machine which performs the test or it may be entered into
database 6 through terminals 16 located elsewhere in the
facility, such as, terminals found in the labs where the
15   analysis is performed or terminals in the medical records
department where medical records staff enter the
handwritten notes generated by the medical staff who
evaluate the patients

Database 6 also stores a broad range of other
20   information which is generated and accessed in the course
of the daily operation of the health care facility. In
other words, the ECG-derived data is integrated into
database 6 with a larger collection of data relating to
the patients treated at the health care facility, the
25   medical staff which provide the health care, the
resources available for administering the care and
information relating to the operational aspects of the
health care facility. For example, it contains patient
billing information generated by the accounting and
30   billing departments, administrative and personnel
information including information about the resident
training program and the experience of the medical staff
within the residency program, and other information which
is necessary to running the facility.

- 10 -

Electrocardiograph 4 provides patient data which
enables the user to classify cardiac patients in a
clinically meaningful way. Meaningful clinical classes
for cardiac patients may be defined in terms of
5   diagnostic criteria which often require both ECG patient
data as well as other clinical data (non-ECG data) for
the patient. For example, the diagnostic criteria for
determining whether a patient has experienced a nonfatal
myocardial infarction includes diagnostic ECG and
10   abnormal enzymes (e.g. creatine phosphokinase (CPK)).
See, for example, Richard F. Gillum, M.D. et al.,
"International diagnostic criteria for acute myocardial
infarction and acute stroke," American Heart Journal, p.
150, (July, 1984), incorporated herein by reference,
15   which presents diagnostic criteria for classifying
cardiac patients. The stored ECG data available through
the electrocardiograph is examined for the presence of
the diagnostic ECG and laboratory results generated
elsewhere in the cardiac care facility (and stored within
20   the same database) are examined for the presence of the
abnormal enzymes, which along with characteristic ECG
findings (e.g. Q waves of greater than 40 msec duration)
confirm and/or define the diagnosis of acute infarction.
Similarly, accurate identification of the patients
25   who have experienced life-threatening hyperkalemic
arrhythmic problems can be accomplished by examining
patient ECG data along with other non-ECG data for the
patient, namely, the patient's potassium level as
determined by a test which is conducted by the
30   laboratory, i.e., another department of the health care
facility. Identification of members of the relevant
diagnostic class need not depend upon the crude and often
inaccurate diagnostic codes which are generated by
medical records personnel who often are relied upon to
35   enter patient medical information into a central

- 11 -

database. Thus, by combining the ECG data with the
general patient information database for the facility,
i.e., the database which includes other clinical
information for patients, the user has immediate access
5   to all data which is necessary for making meaningful
classifications of patients.

For cardiac patients, meaningful clinical classes
may also be defined in terms of the ECG patient data
combined with another category of non-ECG data such as
10   the probability generated by the predictive instrument.
With the electrocardiograph-generated data and the output
of the predictive instrument incorporated into the
general database for the facility, it becomes possible to
easily generate a broad range of meaningful reports on
15   the performance of the facility in providing cardiac
care, i.e., reports based upon valid and meaningful
clinical classifications of patients. Moreover, the
presence of the ECG data and the output of the predictive
instrument in the larger database containing non-ECG data
20   also makes it possible for the facility to generate those
reports in real-time (i.e., while the patient is at the
facility or within a short time after the report is
requested by the user).

The electrocardiograph data within the database
25   also enables the user to define an effective window into
the data which is collected on patients that are
diagnosed and/or treated by a health care facility. More
specifically, it enables the user to produce reports
about the process of care for cardiac patients which are
30   based on meaningful clinical classes.

Moreover, since the electrocardiograph is a
cardinal piece of equipment in the diagnosis and
treatment of all patients passing through the facility
that are suspected of having cardiac problems, it assures
35   that the database is complete. That is, its use in the

- 12 -

clinical information reporting system to create a patient
record within the general database (or to add ECG data to
an already existing patient record) for every potential
cardiac patient assures that the underlying database

5   includes all patients who had cardiac problems. Thus,
any report generated from that database about cardiac
care will more accurately reflect the actual care being
provided by the facility. Since all patients who
received an electrocardiograph are automatically added to

10 the database, the user may be reasonably confident that
the report does not exclude cardiac patients who have
been treated by the facility but through oversight or
error were not added to the database. For example, under
current practice patients erroneously not admitted to the

15 hospital have no in-patient records or data, and errors
cannot be found for that population. Also since the user
can sort and report operational and process of care data
based upon ECG based criteria, the user has greater
confidence in the accuracy of the identification of

20 cardiac problem types. This is particularly important
for generating reliable and accurate risk management,
quality assurance and utilization review reports for the
health care facility.

    The report generating features available through

25 the database software may be used to generate such
reports. Since the ECG-related patient data is present
within the general database, the database software can be
used to sort and/or present patient data based on ECG-
based diagnostic class criteria.

30   The reports of particular importance and which
have not previously been available to the administrator
of the health care facility, the health care insurer, to
malpractice litigation risk management personnel or to
hospital resource utilization review functions are those

35 which relate to the process of care provided by the

- 13 -

facility for clinical classes defined at least in part by
ECG data. "Process of care" analysis is to be
distinguished from "outcome" analysis, which looks at the
results of the medical intervention, and from "structure"
5   analysis, which looks at the physical makeup, condition
and quality of the health care facility. In general,
"process of care" concerns the type and quality of the
actual medical care which is provided to patients. The
following list suggests several examples of measures of
10   process of care:

    Were patients with acute myocardial infarction
    admitted to the CCU?

    Were patients with hyperkalemic arrhythmias
    appropriately treated with agents to lower their
15   potassium level?

    Do patients experiencing cardiac ischemia-related
    chest pain get nitroglycerine within five minutes
    of chest pain onset?

    Are patients with cardiogenic shock given a Swan-
20   Ganz catheter and appropriate medications?

    Were patients triaged home from the ER of
    appropriately low likelihood (e.g. by the
    predictive instrument) of acute ischemia?

    Process of care information may be derived from
25   operational data stored within the database. The
operational data might include, for example:

    credentials and training information on the
    physicians and other members of the medical staff;

    billing information which indicates the types of
30   services that were provided to patients;

    administrative information indicating such things
    as the length of stay;

    data from real-time hospital operations;

    data from pharmacy records;

- 14 -

triage location data;

billing information for the responsible MD;

lab data;

ICU nursing records; and

5   orders for devices (e.g. Swan-Ganz catheters).

Examples of a variety of process of care reports
that may be generated in real-time from the database are
shown in Figs. 3-6.

Fig. 3 is a report of the total number of AMI

10   patients who were sent to each triage location, i.e.,
CCU, ward or home, and the percentage of each group that
died. The members of the relevant population (i.e., the
members of the diagnostic class) are determined by ECG
criteria (e.g. Q wave AMI) and CPK laboratory test

15   results. The triage decision, i.e., where the AMI
patient was sent is determined from billing and hospital
information databases. Such a report is useful for
quality assurance or risk management purposes in
evaluating the correctness of the triage decisions that

20   are being made.

Fig. 4 is a report of the mean probability of
acute cardiac ischemia (ACI) as a function of where
people were sent (i.e., as a function of the triage
decision) and as a function of time period. The leftmost

25   set of bars presents the mean probability for all
patients seen in the emergency room (ER). The next three
sets of bars present the mean probability for patients
sent to each of the three triage locations. In each set
of bars the left bar reports the mean probability for the

30   cumulative quarter from September 1990 through December
1990 and the right bar reports the statistics for January
1991. In this case, the predictive instrument which is
used operates as described in the previously mentioned
Pozen et al. reference. That is, the predictive

- 15 -

instrument uses the ECG data for each patient to generate
a probability that the patient was experiencing ACI.

The information reported in Fig. 4 is useful for
risk management, utilization review, and quality
5   assurance purposes, to name a few. For example, it helps
assess who is being sent to the CCU and whether those
patients really need CCU care. A low mean probability of
ACI for the CCU patients would suggest that people are
being sent to the CCU who might more appropriately be
10   handled by the ward or who even would be sent home.

Fig. 5 is a report of the mean probability of ACI
as a function of triage decision and as a function of the
identity of the treating physician. The treating
physicians are identified as Drs. A through E. Such a
15   report is useful for determining another process of care
concern, namely, is each of the doctors giving
appropriate care. It could be used to identify those
doctors, if any, who were improperly sending people with
high ACI probabilities home and those doctors, if any,
20   who were inappropriately using the limited CCU resources
on patients with low ACI probabilities.

Fig. 6 is a report of the mean probability of ACI
as a function of the triage decision and as a function of
the residency training year of the treating resident
25   physician. Such a report is useful for determining the
effectiveness of the training of the resident physicians.

Other embodiments are within the following claims.
For example, other monitoring devices (e.g. neonatal
heart monitors) also play a correspondingly central role
30   in diagnosing patient problems. Incorporating the output
from such monitoring devices into the general operational
database for the facility gives the user of the database
a very valuable window through which to view all other
patient related data in the database. That is, it
35   enables the user to define meaningful clinical classes

based in part on such monitoring data and to then
generate in real-time process of care reports for such
clinical classes of patients.

What is claimed is:

- 17 -

<u>Claims</u>

1.   A clinical information reporting system for
use with an electronic database for a health care
facility, said electronic database containing records for
5   a group of patients and operational information which is
accessed and used during the course of operation of the
facility, said records containing clinical information
for said group of patients, said reporting system
comprising:

10   an electrocardiograph which generates ECG-related
data for the group of patients;
database application logic for incorporating the
ECG-related data for said group of patients into said
database; and

15   report generating logic for generating a process
of care report from the information stored in said
database, said process of care report presenting selected
process of care information derived from said database as
a function of a clinically meaningful class of said group
20   of patients, wherein said clinically meaningful class is
defined at least in part in terms of the ECG-related data
supplied by said electrocardiograph and stored within
said database.

2.   The clinical information reporting system of
25   claim 1 wherein each of said patient records for a group
of patients contains non-ECG related clinical information
and wherein said clinically meaningful class is defined
in terms of the ECG-related data supplied by said
electrocardiograph and stored within said database and
30   non-ECG related clinical information stored within said
database.

3.   The clinical information reporting system of
claim 2 wherein said non-ECG related clinical information

includes laboratory test results of blood enzyme analyses
and wherein said clinically meaningful class is defined
in terms of the ECG-related data supplied by said
electrocardiograph and stored within said database and
5   the presence of an abnormal blood enzyme as indicated by
said laboratory test results stored in said database.

4.   The clinical information reporting system of
claim 3 wherein said abnormal blood enzyme is CPK.

5.   The clinical information reporting system of
10   claim 1 wherein said database includes administrative
information which is accessed and updated during the
course of operation of the health care facility and
wherein said process of care information is derived at
least in part from said administrative information.

15   6.   The clinical information reporting system of
claim 1 wherein said database includes patient billing
information which is accessed and updated during the
course of operation of the health care facility and
wherein said process of care information is derived at
20   least in part from said patient billing information.

7.   The clinical information reporting system of
claim 1 wherein said database contains triage decisions
for said group of patients and wherein said process of
care report reports triage decisions for said clinically
25   meaningful class of said group of patients.

8.   A clinical information reporting system for
use with an electronic database for a health care
facility, said electronic database containing records for
a group of patients and operational information which is
30   accessed and used during the course of operation of the

- 19 -

facility, said records containing clinical information
for said group of patients, said reporting system
comprising:

     an electrocardiograph which generates ECG-related
5   data for the group of patients;

     a predictive instrument which receives from said
electrocardiograph ECG data for each patient of said
group of patients and which computes a probability for
each patient therefrom, said computed probability for
10 each patient being a probability that patient is
experiencing a cardiac problem;

     database application logic for incorporating said
ECG-related data for said group of patients and the
computed probability for each patient into said database;
15 and

     report generating logic for generating a process
of care report from the information stored in said
database, said process of care report presenting selected
process of care information derived from said database as
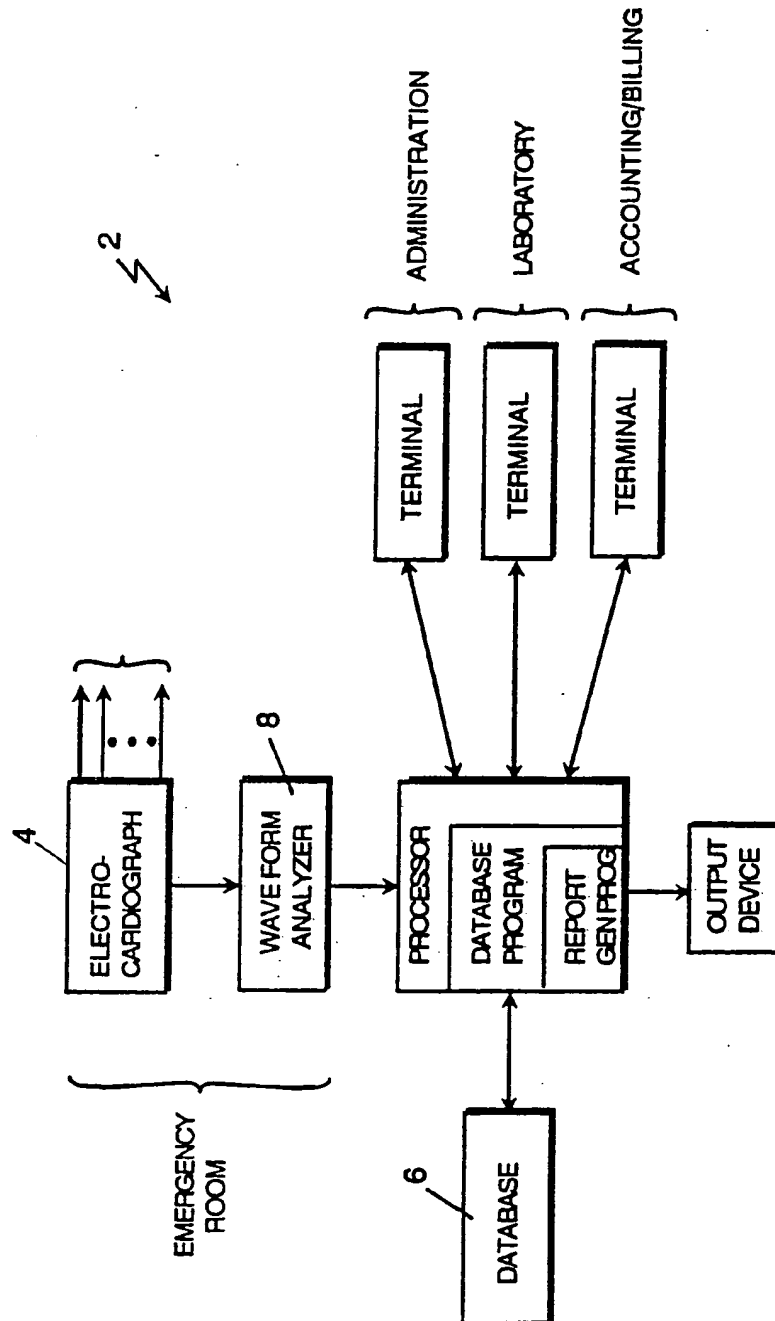20 a function of the computed probabilities supplied by said
predictive instrument.

FIG. 1

2/6

Variable	Coefficient (bi)		Value (x)*
CONSTANT (b$_0$)	-3.933		
CPAIN	1.231	Chest or left arm pain/pressure	1
		Not present	0
SX1CPAIN	0.882	Chest or left arm pain chief complaint	1
		Otherwise	0
MALESEX	0.712	Male	1
		Female	0
AGE	-1.441	Patient age 40 or less	1
		Otherwise	0
AGE50	0.667	Patient age greater than 50	1
		Otherwise	0
SEXAGE50	-0.426	Male patient age greater than 50	1
		Otherwise	0
QWAVE	0.616	ECG Q waves present	1
		Otherwise	0
STEL	0.314	ECG S-T segment elevated 2mm or more	2
		ECG S-T segment elevated 1-2mm	1
		Otherwise	0
STDEP	0.993	ECG S-T segment depressed 2mm or more	2
		ECG S-T segment depressed 1-2mm	1
		ECG S-T segment depressed 0.5-1mm	0.5
		Otherwise	0
TWEL	0.095	ECG T waves elevated ("hyperacute")	1
		Otherwise	0
TWINV	1.127	ECG T-waves inverted 5mm or more	2
		ECG T-waves inverted 1-5mm	1
		ECG T-waves flat	0.5
		Otherwise	0
TWISTDEP	-0.314	Both STDEP and TWINV not 0	1
		Otherwise	0

FIG. 2
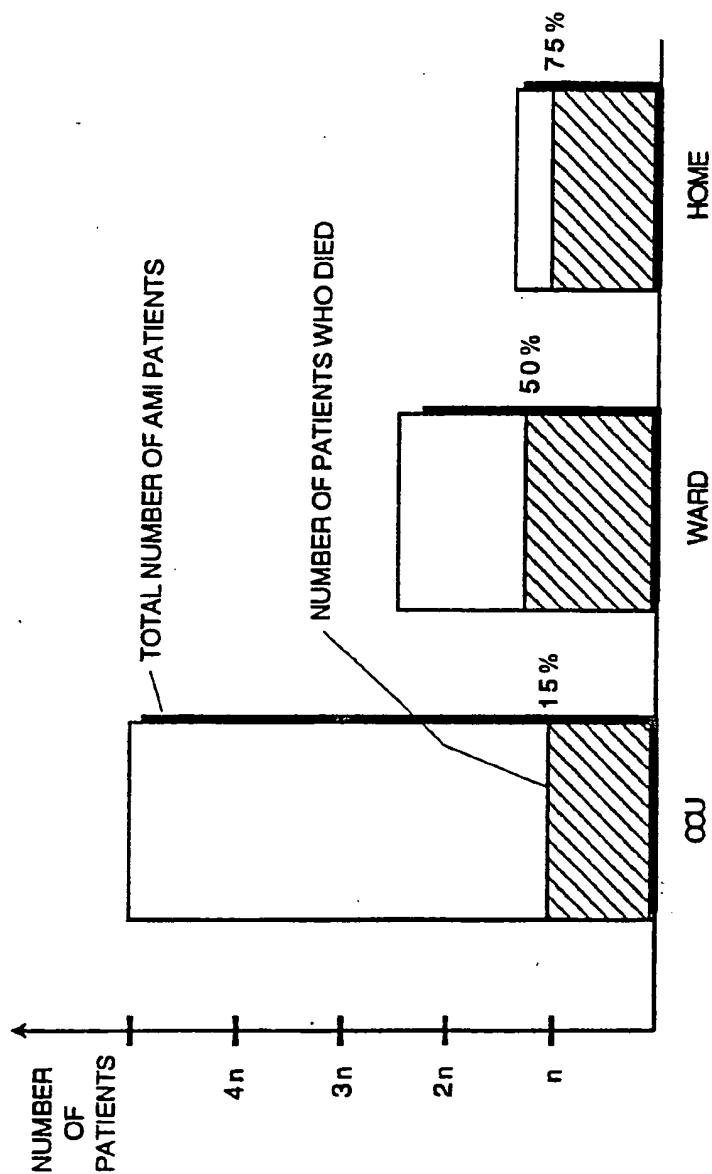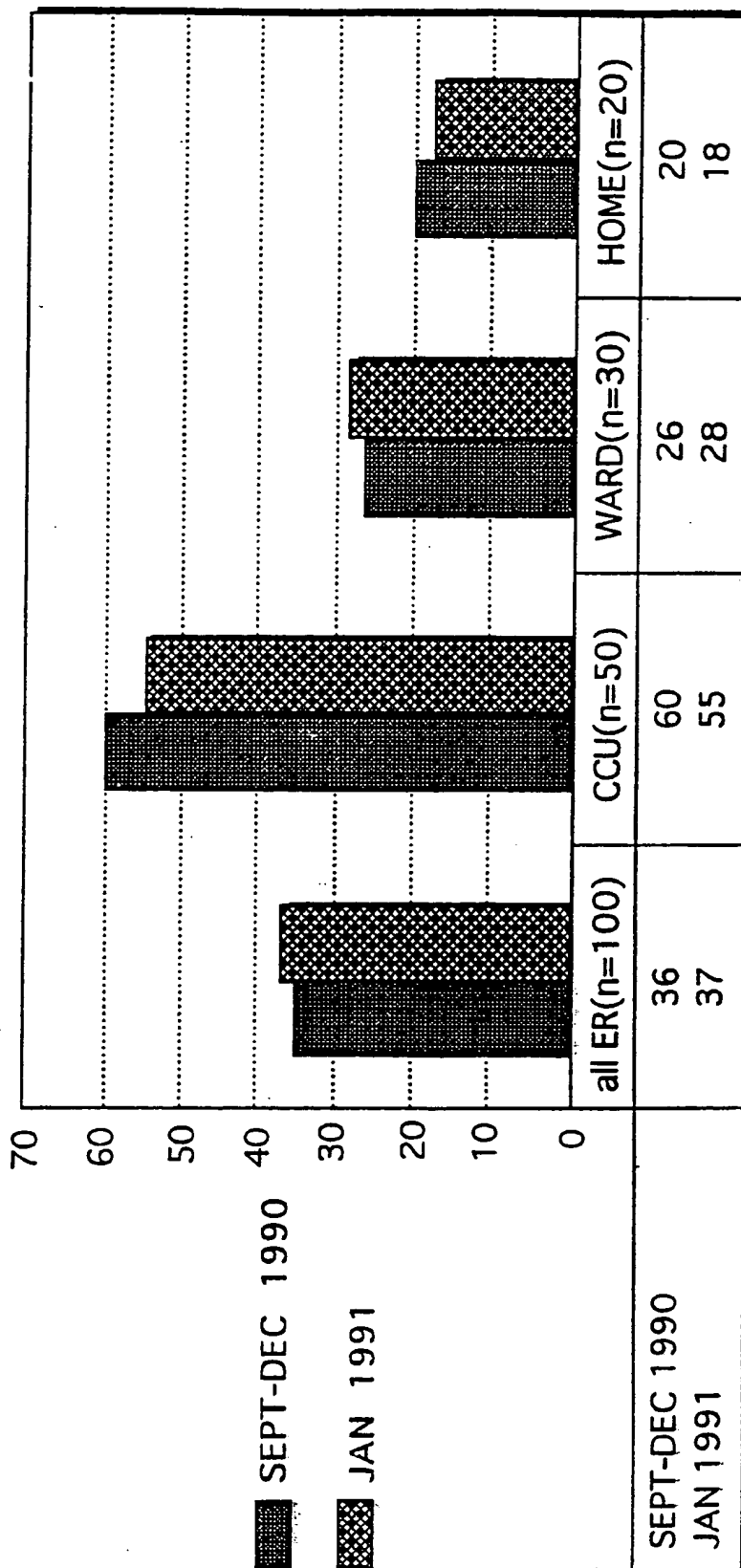
FIG. 3

Probability of Acute Cardiac Ischemia
Mean ACI probability by triage decision
Jan. v. Cumulative Quarter

	all ER(n=100)	CCU(n=50)	WARD(n=30)	HOME(n=20)
SEPT-DEC 1990	36	60	26	20
JAN 1991	37	55	28	18

% probability of ACI

FIG. 4

Probability of Acute Cardiac Ischemia
Mean ACI probability by triage decision and physician

	all ER(n=100)	CCU(n=50)	WARD(n=30)	HOME(n=20)
Dr. A	36	60	26	20
Dr. B	37	55	28	18
Dr. C	36	59	38	12
Dr. D	38	65	24	10
Dr. E	39	78	30	5
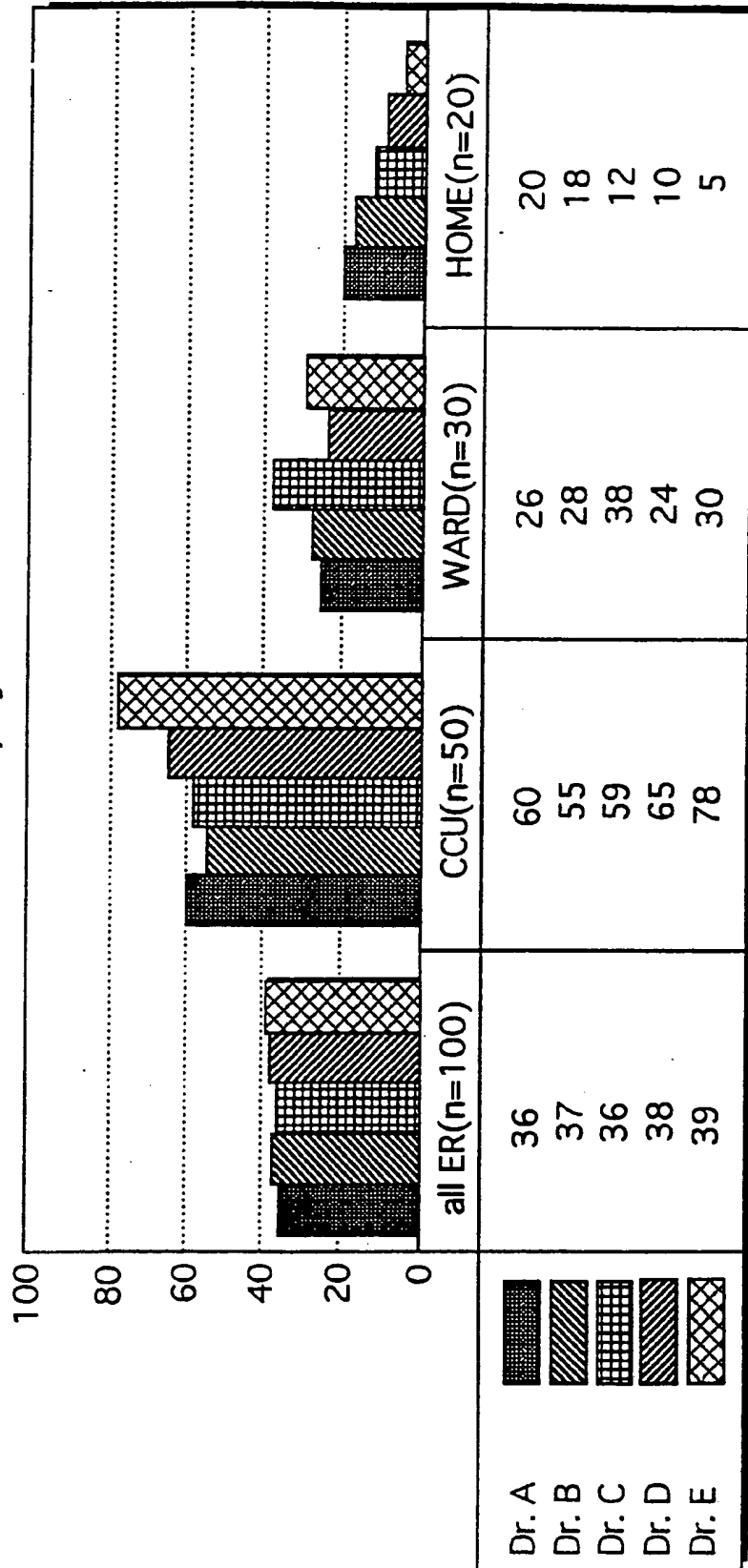
% probability of ACI

FIG. 5

Probability of Acute Cardiac Ischemia

Mean ACI probability by triage decision
and resident training year
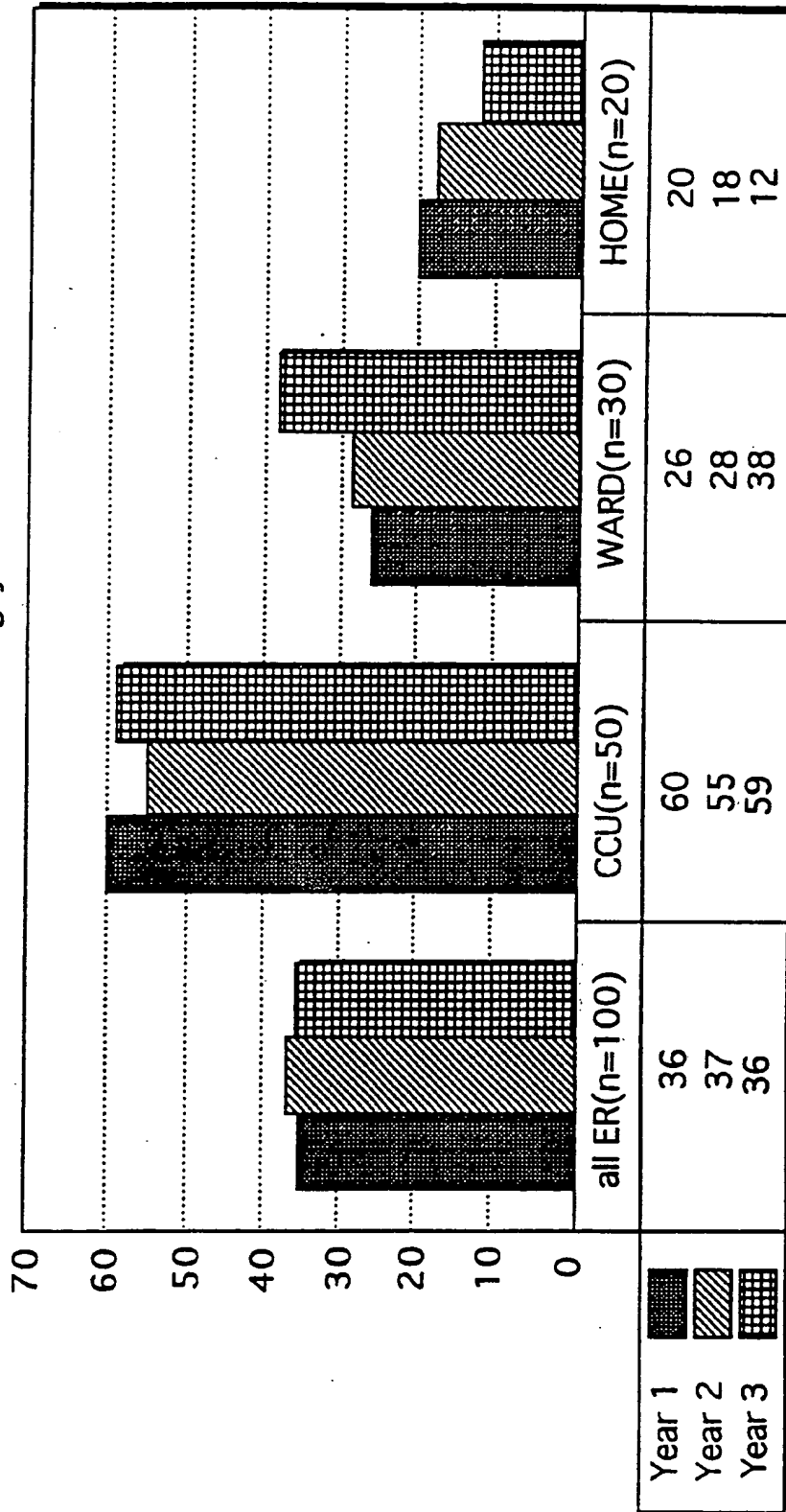
	all ER(n=100)	CCU(n=50)	WARD(n=30)	HOME(n=20)
Year 1	36	60	26	20
Year 2	37	55	28	18
Year 3	36	59	38	12

% probability of ACI

FIG. 6

INTERNATIONAL SEARCH REPORT

A.	CLASSIFICATION OF SUBJECT MATTER

IPC(5)   :A61B 05/04
US CL   :128/696

According to International Patent Classification (IPC) or to both national classification and IPC

B.	FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. :   128/695,364/413.06,128/702-705

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C.	DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,679,144 (COX ET AL.) 07 July 1987, See entire document.	1-8
A P	US, A, 5,046,499 (BERGER) 10 September 1991, See entire document.	1-8
X	US, A, 4,998,535 (SELKER ET AL.) 12 March 1991, See entire document.	1-8
X P	US, A, 4,945,477 (EDWARDS) 31 July 1991, See entire document.	1-7
A	US, A, 4,957,115 (SELKER) 18 September 1990, See entire document.	1-8
A	US, A, 4,893,270 (BECK ET AL.) 09 January 1990, See entire document.	1-8
A	US, A, 4,610,254 (MORGAN ET AL.) 09 September 1986, See entire document.	1-8
A	US, A, 4,315,309 (COLI) 09 February 1982, See entire document.	1-8

[X]   Further documents are listed in the continuation of Box C.   [ ]   See patent family annex:

*	Special categories of cited documents:
"A"	document defining the general state of the art which is not considered to be part of particular relevance
"E"	earlier document published on or after the international filing date
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O"	document referring to an oral disclosure, use, exhibition or other means
"P"	document published prior to the international filing date but later than the priority date claimed

"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&"	document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 JULY 1992	- ~ NOV 1992

Name and mailing address of the ISA/	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	JEFFREY R. JASTRZAB
Facsimile No. NOT APPLICABLE	Telephone No. (703) 308-2097

Form PCT/ISA/210 (second sheet)(July 1992)*

International application No.

PCT/US92/05232

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	The New England Journal of Medicine, 17 May 1984, (M.W. POZEN), "A Predictive Instrument to Improve Coronary Care Unit Admission Practices in Acute Ischemic Heart Disease", Volume 310, pp. 1273-1278, entire document.	1-8
A	American Heart Journal, July 1984, (R.F. GILLUM, M.D. ET AL.) "International diagnostic criteria for acute myocardial infraction and acute stroke", page 150, entire document.	1-8